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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,436	06/08/2000	Dosuk D. Lee	04712/02000F	2313

23483 7590 09/16/2003

HALE AND DORR, LLP  
60 STATE STREET  
BOSTON, MA 02109

EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/284,436

Applicant(s)

LEE ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 128 and 130-143 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 128 and 130-143 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 128 and 130-143 are pending in this application.

#### ***Drawings***

1. The drawing(s) filed June 8, 2000 are accepted by the Draftsperson under 37 CFR 1.184 or 1.152.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on February 7, 2000 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Claim Objections***

3. Claim 133 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 133 depends upon claim 129 which has been cancelled. For the purposes of examination the examiner exam claim 133 depending from claim 128.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 132 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 132 recites the limitation "the at least one bone-resorbing cell" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. It is the opinion of the examiner that claim 132 should have depended from claim 131, not from claim 128. For the purposes of examination claim 132 will be read as depending from claim 131,

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 128 and 136-141 are rejected under 35 U.S.C. 102(b) as being anticipated by Constanz et al. (US Pat. No. 5,336,264).

Constanz et al. discloses a composition comprising calcium phosphate. Column 3, lines 6-21 teach a method of making the calcium phosphate mineral composition.

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Column 6, lines 38-62 teach that a variety of additives may be added such as proteins, bone associated proteins that may be added to modify the physical properties of the composition, enhance resorption, bone formation, growth of osteoclasts and/or osteoblasts, etc. Column 3, lines 38-62 describes in detail particular in lines 22-46 the first stage involving mixing of the primary calcium sources with an acidic neutralizing phosphate source in combination with monetite, wherein the ratio of calcium to phosphate is 1.1:1 to 2:1. Column 6, lines 9-10 teach the dry material is combined with a physiologically acceptable lubricant such as sterile water.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 128 and 130-143 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (US Pat. No. 6,132,463).

Lee et al. discloses a poorly crystalline (PCA) calcium phosphate material that has excellent biocompatibility, resorbability, and processability characteristics (col. 3, lines 57-60. Column 4, lines 39-53 teach the present invention comprising the PCA material and at least one cell and that the implants may also contain biologically active

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agents such as factors. Column 6, lines 42-55 teach that the PCA material of the present invention may be prepared with any variety of additives, and/or as a composite. In some cases it is desirable to add factors to the PCA material that can affect cell growth, differentiation and/or localization. Column 8, lines 17-18 teach that one or more additives may be introduced into the PCA material before or after seeding. Column 15, lines 8-20 teach a composition comprising the amorphous calcium phosphate of example 1 (col. 13, lines 29- col. 14, line 24) that is mixed with dicalcium phosphate dihydrate at a 50:50wt %. It is also taught the water is added to the powder mixture to yield a paste-like consistency.

### ***Conclusion***

7. Claims 128 and 130-143 stand rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Konata M. George', with a stylized flourish at the end.

Konata M. George  
Patent Examiner  
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